# Critical Issues: Emerging and New Plant and Animal Pests and Diseases

# FY 2008 Request for Applications #2

**APPLICATION DEADLINE: June 18, 2008** 



**U.S. Department of Agriculture** 



Cooperative State Research, Education, and Extension Service

# COOPERATIVE STATE RESEARCH, EDUCATION, AND EXTENSION SERVICE; U.S. DEPARTMENT OF AGRICULTURE

CRITICAL ISSUES: EMERGING AND NEW PLANT AND ANIMAL PESTS AND DISEASES

#### INITIAL ANNOUNCEMENT

**CATALOG OF FEDERAL DOMESTIC ASSISTANCE:** This program is listed in the Catalog of Federal Domestic Assistance under 10.200 (Special Research Grants).

**DATES:** Applications must be received by close of business (COB) on June 18, **2008** (5:00 p.m. Eastern Time). Applications received after this deadline will normally not be considered for funding. Comments regarding this request for applications (RFA) are requested within six months from the issuance of this notice. Comments received after that date will be considered to the extent practicable.

STAKEHOLDER INPUT: The Cooperative State Research, Education, and Extension Service (CSREES) is requesting comments regarding this RFA from any interested party. These comments will be considered in the development of the next RFA for the program, if applicable, and will be used to meet the requirements of section 103(c)(2) of the Agricultural Research, Extension, and Education Reform Act of 1998 (7 U.S.C. 7613(c)(2)). This section requires the Secretary to solicit and consider input on a current RFA from persons who conduct or use agricultural research, education and extension for use in formulating future RFAs for competitive programs. Written stakeholder comments on this RFA should be submitted in accordance with the deadline set forth in the DATES portion of this Notice.

Written stakeholder comments should be submitted by mail to: Policy, Oversight, and Funds Management Staff; Office of Extramural Programs; Cooperative State Research, Education, and Extension Service; USDA; STOP 2299; 1400 Independence Avenue, SW; Washington, DC 20250-2299; or via e-mail to: <a href="mailto:RFP-OEP@csrees.usda.gov">RFP-OEP@csrees.usda.gov</a> (This e-mail address is intended only for receiving comments regarding this RFA and not requesting information or forms.) In your comments, please state that you are responding to the Critical Issues: Emerging and New Plant and Animal Pests and Diseases RFA.

**EXECUTIVE SUMMARY:** CSREES announces the availability of grant funds and requests applications for the Critical Issues program to perform critical research activities related to time-critical, emerging plant and animal pest and disease issues. The amount of funds available for support of this particular solicitation is approximately \$500,000. CSREES anticipates funding critical research projects in Johne's Disease Vaccination Modeling and Porcine High Fever Disease (PHFD). The program is designed to provide one-time seed funding to help initiate work requiring immediate attention until other longer-term resources can be secured to address the issue. CSREES intends to solicit applications multiple times during FY 2008 and FY 2009 to address specific new or emerging issues.

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#### PART I—FUNDING OPPORTUNITY DESCRIPTION

## A. Legislative Authority and Background

The authority for this program is contained in Section 2(c)(1)(B) of the Act of August 4, 1965, Public Law No. 89-106, as amended (7 U.S.C. 450i (c)(1)(B)). This program supports critical research activities related to time-critical, emerging plant and animal pest and disease issues.

## **B. Purpose and Priorities**

CSREES announces the availability of grant funds and requests applications for the Critical Issues program to perform critical research activities related to time-critical, emerging plant and animal pest and disease issues. The program is designed to provide one-time seed funding to help initiate work requiring immediate attention until other longer-term resources can be secured to address the issue. CSREES intends to solicit applications multiple times during FY 2008 and FY 2009 to address specific new or emerging issues. For this particular solicitation, CSREES is requesting applications that address specific aspects of the following issues:

- Johne's Disease Vaccination Modeling
- Porcine High Fever Disease (PHFD)

#### Priority will be given to proposed projects that:

- 1) Are staffed by collaborative teams who document their experience in making optimal use of existing local, regional, and national capabilities and capacities; and
- 2) Demonstrate their experience in conducting time-critical research.

This notice identifies the objectives for Critical Issues projects, the eligibility criteria for projects and applicants, and the application forms and associated instructions needed to apply for a Critical Issues grant. CSREES additionally requests stakeholder input about emerging plant and/or animal pests and diseases from any interested party for use in the development of the next RFA for this program.

#### PART II—AWARD INFORMATION

# A. Available Funding

There is no commitment by USDA to fund any particular application or to make a specific number of awards. Approximately \$500,000 will be available to support Critical Issues applications submitted in response to this solicitation for project periods of up to 2 years with the option for a 1 year no cost extension.

# **B.** Types of Applications

Only **new applications** are to be submitted in response to this RFA. A **new application** is a project application that has not been previously submitted to the Critical Issues Program. All new applications will be reviewed competitively using the selection process and evaluation criteria described in Part V—Application Review Requirements.

# C. Project Types

Johne's Disease Vaccination Modeling: Impacts on the Bovine Tuberculosis (TB) Eradication and the Voluntary Bovine Johne's Disease Control Programs – CSREES anticipates funding up to 2 applications for up to \$200,000 each.

Current estimates indicate that up to 70 percent of U.S. dairy herds, and a smaller percent of beef herds, are infected with Johne's disease. The economic impact to the dairy industry varies widely but Animal and Plant Health Inspection Service (APHIS) estimates are around \$200,000,000/year based on collaborative research conducted by the Centers for Epidemiology and Animal Health, USDA-APHIS, and the Department of Clinical Sciences and Population Sciences, College of Veterinary Medicine, University of Minnesota. Economic impact data from this research, first published as "Herd-level economic losses associated with Johne's disease on US dairy operations" Preventive Veterinary Medicine / Volume 40, Issues 3-4, 11 June 1999, Pages 179-192, has been utilized in several subsequent USDA publications and Fact Sheets on Johne's Disease.

There is a growing consensus among U.S. and international Johne's disease subject matter experts that vaccination may be a cost-effective way to control the spread of Johne's disease. However, there is uncertainty with respect to the potential impacts Johne's vaccination may have on the TB Eradication Program given the phylogenetic relatedness of the two causative mycobacterial agents. The Committee on Johne's Disease of the United States Animal Health Association (USAHA) specifically identified this concern in its "Knowledge Gaps Report" published in the Proceedings of the 109th Annual Meeting of the United States Animal Health Association (2005, p: 416). The ability to take into account the impact of Johne's vaccination on the TB Eradication Program, as well as the Voluntary Bovine Johne's Disease Control Program, will be critical for the USDA – APHIS to respond to the growing stakeholder desire to allow unrestricted vaccine use.

The <u>Voluntary Bovine Johne's Disease Control Program</u> seeks tools that can be used to help predict whether widespread use of Johne's vaccination would have a significant effect on the reduction of Johne's disease infected animals/herds, and what the impacts of vaccination would be on the <u>TB Eradication Program</u>. Furthermore, if there is potential negative impact on the TB Eradication Program, the Voluntary Bovine Johne's Disease Control Program must be able to evaluate alternative criteria for new vaccination products or to develop new vaccine use protocols that would mitigate negative impacts to the Program(s).

Critical Issues applications addressing Johne's Disease Vaccination Modeling should propose to develop predictive model(s) based on currently available information and data pertaining to a variety of relevant parameters. Examples of such parameters are: 1) efficacy of the approved killed vaccine, 2) Caudal Fold TB Test reactor rates and costs with and without vaccination, 3) Comparative Cervical TB Test reactor rates with and without vaccination, and 4) cross-reactivity rates with respect to age of vaccine administration.

Optimally, cost-benefit model(s) developed under this RFA would be flexible enough to enable comparison of a variety of current and hypothetical Johne's disease vaccine management strategies. Model(s) should enable predictive comparative analyses of the impact(s) on the Voluntary Bovine Johne's Disease Control and TB Eradication Programs, for example: 1) using the current licensed vaccine product only, 2) using a new vaccine product that does interfere with TB and Johne's disease testing but prevents or significantly reduces shedding, and 3) using a new product that does not interfere with TB testing but may not be 100% effective in reducing shedding or reducing clinical signs.

The principal research objective will be development of predictive tools using, as appropriate, scientific principals and methodologies derived from the fields of epidemiology, risk analysis, systems modeling, veterinary microbiology and immunology, and agricultural economics. Strategies for validation of model(s) should be included in the proposed plan of work, and full characterization of limitations of the model(s) should be provided. It is understood that the model development process could lead to a first-generation tool that may or may not be sufficiently robust to effectively guide decision-making with respect to developing control program policies. In this regard, it is expected that work products from the funded project may ultimately serve as foundational or pilot studies that will in turn underpin future development of a fully functional model.

Johne's Disease Vaccination Modeling applicants should assemble from the literature, and from existing programs devoted to Johne's Disease management and research (e.g., Johne's Disease Integrated Program (JDIP) and the Voluntary Bovine Johne's Disease Control Program), relevant information, methodologies, and data required to construct and validate a predictive model enabling comparative cost-benefit analysis of implementation of candidate Johne's vaccination strategies. Applications demonstrating evidence of collaboration and communication with existing major programs and initiatives within the at-large Johne's disease scientific community are desirable. Additionally, applications for Critical Issues funding should be innovative and inspire other sources of public and/or private funding to enhance prospects for project success.

# Porcine High Fever Disease (PHFD) – CSREES anticipates funding up to two applications for up to \$200,000 each.

Beginning in 2006, epidemics of severe swine disease, termed "Porcine High Fever Disease (PHFD)", have been reported in Southeast Asia (<u>American Association of Swine Veterinarians</u>). Data from research conducted by Chinese scientists Guang-Zhi Tong, Yan-Jun Zhou, Xiao-Fang Hao, Zhi-Jun Tian, Tong-Qing An, Hua-Ji Qiu resulted in the article "<u>Highly pathogenic porcine reproductive and respiratory syndrome, China</u>", and was first published online in <u>Emerging Infectious Diseases</u>, <u>Sept, 2007</u>. Investigations into these cases consistently identified porcine reproductive and respiratory syndrome virus (PRRSV). This virus has been implicated as the primary cause of these epidemics (<u>USDA – APHIS: Veterinary Services – Centers for Epidemiology and Animal Health, August 2007).</u>

Although PRRSV is known to contribute to the disease, in the United States it has not been associated with such severe diseases as have been officially reported in China, Vietnam, and informally in other neighboring countries. Applicants should propose to study tissue samples recovered from a Vietnam epidemic of PHFD using animal infection models and perform genetic analyses of the swine pathogen(s) identified. Due to the potential for previously unidentified or unknown pathogens to have a role in the PHFD syndrome, the live-animal infection work is to be done in a laboratory that can ensure biosecurity, can prevent accidental release of pathogens and can protect the U.S. swine herd from infection.

These studies are expected to provide insight into the contributing role of PRRSV and other pathogens in the Southeast Asia epidemics and into the epidemiology of PHFD. Insights gleaned from this research will benefit the U.S. pork industry by providing advance knowledge about the contribution of possible new virulence features of the PRRSV isolate that has emerged in swine in SE Asia, but has yet to appear in North America; and about other pathogens that may be identified in the course of this research.

PHFD applicants should propose collaborative research activities designed to determine the mechanisms of pathogenesis and the etiologic agents responsible for the syndrome identified as PHFD. Using archived or newly collected tissue samples recovered from foreign-source pigs known to be positive for PHFD, studies should be conducted that focus on 1) isolation of unknown disease agent(s) that could be interacting and/or synergizing with PRRSV to cause PHFD, 2) descriptive, functional and comparative molecular genetic analyses of PRRSV and other identified potential disease agents, 3) development of a model of pathogenesis, and 4) assessment of the threat PHFD poses to the U.S. national porcine population by evaluation of relative host strain susceptibility, characterization of the role of environment in PHFD ecology, and characterization of the dynamics of disease spread. Applicants must describe specialized facilities and collaborations necessary for work that may involve select agents or other highconsequence foreign animal disease agents. Investigators must stipulate that work will be carried out in accordance with all relevant APHIS policies, regulations and guidance pertaining to foreign animal disease agents. For example, plans for access to appropriate biosafety level laboratory space, technical staff trained in the safe use of highly infectious agents, and collaborations with DHS and/or ARS scientists at the Foreign Animal Disease Diagnostic

Laboratory (FADDL) at Plum Island should be clearly described in the application. Applications demonstrating assembly of collaborative teams that make optimal use of existing local, regional, and national capabilities and capacity are desirable. Additionally, applications for Critical Issues funding should be innovative and inspire other sources of public and/or private funding to enhance prospects for project success.

#### **D.** Scientific Peer Review

Subsection (c)(5) of the Competitive, Special, and Facilities Research Grant Act, as amended (7 U.S.C. 450i(c)(5)) requires applicants to conduct scientific peer review of their proposed research activities in accordance with regulations promulgated by the Secretary prior to the Secretary making a grant award under this authority. Regulations implementing this requirement are set forth in 7 CFR part 3400.20. The regulations impose the following requirements:

- (1) Scientific peer review. Prior to the award of a standard or continuation grant by CSREES, any proposed project shall have undergone a review arranged by the grantee. For research projects, the review arranged by the grantee must be a scientific peer review conducted in accordance with 7 CFR 3400.21.
- (2) Credible and independent review. A review arranged by the grantee must provide for a credible and independent assessment of the proposed project. A credible review is one that provides an appraisal of technical quality and relevance sufficient for an organizational representative to make an informed judgment as to whether the applications is appropriate for submission for Federal support. To provide for an independent review, such review may include USDA employees, but should not be conducted solely by USDA employees.
- (3) Notice of completion and retention of records. A notice of completion of the review shall be conveyed in writing to CSREES as part of the Other Attachments (Field 11. of the R&R Other Project Information Form). The written notice constitutes certification by the applicant that a review in compliance with these regulations has occurred. Applicants are not required to submit results of the review to CSREES; however, proper documentation of the review process and results should be retained by the applicant. Please note: award funds cannot be released until the Scientific Peer Review Certification is received.

#### PART III—ELIGIBILITY INFORMATION

# A. Eligible Applicants

Applications may be submitted by State agricultural experiment stations, land-grant colleges and universities, research foundations established by land-grant colleges and universities, colleges and universities receiving funds under the Act of October 10, 1962 (16 U.S.C. 582a et seq.) McIntire-Stennis Cooperative Forestry Research Act, and accredited schools or colleges of veterinary medicine for the purpose of facilitating or expanding ongoing State-Federal food and agricultural research programs that:

- (i) promote excellence in research on a regional and national level;
- (ii) promote the development of regional research centers;
- (iii) promote the research partnership between the Department of Agriculture, colleges and universities, research foundations, and State agricultural experiment stations for regional research efforts; and
- (iv) facilitate coordination and cooperation of research among States through regional research grants.

Award recipients may subcontract to organizations not eligible to apply provided such organizations are necessary for the conduct of the project. An applicant's failure to meet an eligibility criterion by the time of an application deadline will result in CSREES returning the application without review or, even though an application may be reviewed, will preclude CSREES from making an award.

#### **B.** Cost Sharing or Matching

CSREES does not require matching support for this program and matching resources will not be factored into the review process as evaluation criteria.

#### PART IV—APPLICATION AND SUBMISSION INFORMATION

# A. Address to Request Application Package

Only electronic applications may be submitted via Grants.gov to CSREES in response to this RFA.

Prior to preparing an application, it is suggested that the PD/PI first contact an Authorized Organizational Representative (AOR) to determine if the organization is prepared to submit electronic applications through Grant.gov. If the organization is not prepared, the AOR should see <a href="http://www.grants.gov/applicants/get\_registered.jsp">http://www.grants.gov/applicants/get\_registered.jsp</a> for steps for preparing to submit applications through Grants.gov.

The steps to access application materials are as follows:

- 1. Download and install PureEdge Viewer, a small, free program that provides access to the grant application. See <a href="http://www.grants.gov/help/help.jsp#pureedge">http://www.grants.gov/help/help.jsp#pureedge</a>.
- 2. The application package must be obtained via Grants.gov, go to <a href="http://www.grants.gov/">http://www.grants.gov/</a>, click on "Apply for Grants" in the left-hand column, click on "Step 1: <a href="https://apply.grants.gov/forms\_apps\_idx.html">https://apply.grants.gov/forms\_apps\_idx.html</a>," enter the funding opportunity number USDA-CSREES-OP-001054 in the appropriate box and click "Download Package." From the search results, click "Download" to access the application package.

Contained within the application package is the "<a href="http://www.csrees.usda.gov/funding/grant\_forms/electronic\_app\_guide.pdf">http://www.csrees.usda.gov/funding/grant\_forms/electronic\_app\_guide.pdf</a>"
This Guide contains an introduction and general Grants.gov instructions, information about how to use a Grant Application Package in Grants.gov, and instructions on how to complete the application forms.

**If assistance is needed to access the application package** (e.g., downloading or navigating PureEdge forms, using PureEdge with a Macintosh computer), refer to resources available on the Grants.gov Web site first (http://grants.gov/). Grants.gov assistance is also available as follows:

• Grants.gov customer support Toll Free: 1-800-518-4726

Business Hours: M-F 7:00 am – 9 pm Eastern Standard Time

Email: support@grants.gov

See <a href="http://www.csrees.usda.gov/funding/electronic.html">http://www.csrees.usda.gov/funding/electronic.html</a> for additional resources for applying electronically.

# **B.** Content and Form of Application Submission

Electronic applications should be prepared following Part V and VI of the document entitled "<u>A</u> <u>Guide for Preparation and Submission of CSREES Applications via Grants.gov</u>." This guide is part of the corresponding application package (see Section A. of this Part). The following is **additional information** needed in order to prepare an application in response to this RFA. If there is discrepancy between the two documents, the information contained in this RFA is overriding.

Note the attachment requirements (e.g., portable document format) in Part III section 3. of the CSREES Grants.gov Application Guide available with the Application Package at Grants.gov. **ANY APPLICATIONS CONTAINING NON-PDF DOCUMENTS WILL BE AT RISK OF BEING EXCLUDED FROM CSREES REVIEW.** Partial applications will be excluded from consideration. With documented prior approval, resubmitted applications will be accepted until close of business (COB) on the closing date in the RFA.

If you do not own PDF generating software, Grants.gov provides online tools to assist applicants. Users will find PDF Conversion programs at the following link: <a href="http://www.grants.gov/help/help.jsp#pdf">http://www.grants.gov/help/help.jsp#pdf</a> conversion programs#pdf conversion programs.

# 1. R&R Other Project Information Form

Information related to the questions on this form is dealt with in detail in Part V, 3. of the CSREES Grants.gov Application Guide.

- a. Project Summary/Abstract (Field 6. on the Form). The summary should also include the relevance of the project to the goals of the Critical Issues Program and to performing critical research activities related to time-critical, emerging plant and animal pest and disease issues.
- b. Project Narrative (Field 7. on the Form).

PLEASE NOTE: The Project Narrative shall not exceed **25** pages of written text and up to **5** additional pages for figures and tables. This maximum **30** pages has been established to ensure fair and equitable competition. The Project Narrative must include all of the following:

- (1) Objectives. Clear, concise, complete, and logically arranged statement(s) of the specific aims of the proposed effort to the segment of the time critical research activities contained in the application must be included.
- (2) Procedures. The procedures or methodology to be applied to the proposed effort should be explicitly stated. This section should include but not necessarily be limited to: (i) a description of the proposed investigations and/or experiments in the sequence in which it is planned to carry them out; (ii) techniques to be employed, including their feasibility; (iii) kinds of results expected; (iv) means by which data will be analyzed or interpreted; (v) pitfalls which might be encountered; and (vi) limitations to proposed procedures.

- (3) Justification. This section should include in-depth information on the following, when applicable: (i) estimates of the magnitude of the problem and its relevance to ongoing State-Federal food and agricultural research programs; (ii) importance of starting the work during the current FY; and (iii) reasons for having the work performed by the proposing institution; (iv) evidence of collaboration and experience in making optimal use of existing local, regional, and national capabilities and capacities; (v) level of innovation; and (vi) demonstrated experience in conducting time-critical research.
- (4) Literature Review. A summary of pertinent publications with emphasis on their relationship to the effort being proposed should be provided and should include all important and recent publications from other institutions, as well as those from your institution. The citations themselves should be accurate, complete, and written in an acceptable journal format.
- (5) Current Work. Current unpublished institutional activities to date in the program area under which the application is being submitted should be described.
- (6) Project Timetable. The application should outline all important phases as a function of time for the entire project period.
- (7) Demonstrate assembly of collaborative teams that make optimal use of existing local, regional, and national capabilities and capacity.
- (8) Demonstrate experience in conducting time-critical research
- (9) Additional Project Specific Information:

## <u>Information for Inclusion Specific to Johne's Disease Vaccination Modeling Applications:</u>

- a. Clearly describe development of predictive model(s) based on currently available information and data pertaining to a variety of relevant parameters (as described in Part IIC).
- b. Describe level and method(s) of proposed collaboration and communication with existing major programs and initiatives within the at-large Johne's Disease scientific community.

## **Information for Inclusion Specific to PHFD Applications:**

- a. Clearly describe proposed collaborative research activities designed to determine the mechanisms of pathogenesis and the etiologic agents responsible for the syndrome identified as PHFD (as described in Part IIC).
- b. Provide a comprehensive description of specialized facilities and collaborations necessary for work that may involve select agents or other high-consequence foreign animal disease agents.
- c. Describe research and oversight protocols to ensure that work will be carried out in accordance with all relevant APHIS policies, regulations and guidance pertaining to foreign animal disease agents.

# 2. R&R Senior/Key Person Profile (Expanded)

Information related to the questions on this form is dealt with in detail in Part V, 4. of the CSREES Grants.gov Application Guide.

Also, you must attach "Current and Pending Support" information. See CSREES Grants.gov Application Guide, Part 4.3 for guidelines and information format for each senior/key person identified. Note: Even if no funding is currently reported under the "Active" section of this attachment, you must still list information for this grant application under the "Pending" section of this attachment for each senior/key person identified.

3. <u>R&R Personal Data</u> – As noted in Part V, 5., the submission of this information is voluntary and is not a precondition of award. PLEASE DO NOT PROVIDE THE SOCIAL SECURITY NUMBER OF PROJECT DIRECTOR / PRINCIPAL INVESTIGATOR.

#### 4. R&R Budget

Information related to the questions on this form is dealt with in detail in Part V, 6. of the CSREES Grants.gov Application Guide.

# 5. Supplemental Information Form

Information related to the questions on this form is dealt with in detail in Part VI, 1. of the CSREES Grants.gov Application Guide.

- a. Program Code (Field 2. on the Form). Enter the program code name "Critical Issues: Emerging and New Plant and Animal Pests and Diseases" and the program code "NI".
- b. Conflict of Interest List (Field 8. on the Form). A conflict of interest list is required under this announcement.

#### C. Submission Dates and Times

Instructions for submitting an application are included in Part IV, Section 1.9 of the CSREES Grants.gov Application Guide.

Applications must be received by Grants.gov by COB on June 18, **2008** (5:00 p.m. Eastern Time). Applications received after this deadline will normally not be considered for funding.

Correspondence regarding submitted applications will be sent using e-mail. Therefore, applicants are strongly encouraged to provide accurate e-mail addresses, where designated, on the SF-424 R&R Application for Federal Assistance.

If the AR has not received correspondence **from CSREES** regarding a submitted application within 30 days of submission of the application, please contact the Program Contact identified in Part VII of the RFA and request the proposal number assigned to the application. **Failure to do so may result in (for competitive programs) the application not being considered for funding by the peer review panel.** Once the application has been assigned a proposal number, this number should be cited on all future correspondence.

# **D. Funding Restrictions**

#### 1. Indirect Costs

Pursuant to Section 1473 of the National Agricultural Research, Extension, and Teaching Policy Act of 1977, as amended, 7 U.S.C. 3319, **indirect costs are not allowable costs under Section 2(c)(1)(B) Special Grant projects,** and no funds will be approved for this purpose. Further, costs that are a part of the institution's indirect cost pool, (e.g., administrative or clerical salaries), may not be reclassified as direct costs for the purpose of making them allowable.

# 2. Building Construction or Renovation

No funds will be awarded for the renovation or refurbishment of research spaces; the purchase or installation of fixed equipment in such spaces; or for the planning, repair, rehabilitation, acquisition, or construction of a building or facility.

#### 3. Tuition Remission

In accordance with Section 1473 of the National Agricultural Research, Extension, and Teaching Policy Act of 1977 (91 Stat. 981), as amended, **tuition remission is not an allowable cost under Section 2(c)(1)(B) projects**, and no funds will be approved for this purpose.

## **E.** Other Submission Requirements

The applicant should follow the submission requirements noted in the document entitled "A Guide for Preparation and Submission of CSREES Applications via Grants.gov."

#### PART V— APPLICATION REVIEW REQUIREMENTS

#### A. General

Each application will be evaluated in a 2-part process. First, each application will be screened to ensure that it meets the administrative requirements as set forth in this RFA. Second, applications that meet these requirements will be technically evaluated by a review panel.

Reviewers will be selected based upon training and experience in relevant scientific, extension, or education fields, taking into account the following factors: (a) The level of relevant formal scientific, technical education, or extension experience of the individual, as well as the extent to which an individual is engaged in relevant research, education, or extension activities; (b) the need to include as reviewers experts from various areas of specialization within relevant scientific, education, or extension fields; (c) the need to include as reviewers other experts (e.g., producers, range or forest managers/operators, and consumers) who can assess relevance of the applications to targeted audiences and to program needs; (d) the need to include as reviewers experts from a variety of organizational types (e.g., colleges, universities, industry, state and Federal agencies, private profit and non-profit organizations) and geographic locations; (e) the need to maintain a balanced composition of reviewers with regard to minority and female representation and an equitable age distribution; and (f) the need to include reviewers who can judge the effective usefulness to producers and the general public of each application.

#### **B.** Evaluation Criteria

The evaluation criteria and weights below will be used in reviewing applications submitted in response to this RFA:

#### **General Evaluation Criteria: (40 Points total)**

- 1. Feasibility of attaining objectives (10 points);
- 2. Relevance and importance of the proposed research to achieving the program objectives (as described in Part IIC) (15 points);
- 3. Professional training and experience of key project personnel (5 points);
- 4. Adequacy of facilities and equipment (5 points)(NOTE: for PHFD applications, this 5points will be in addition to the consideration of Specific Criteria for PHFD Applications #2., as listed below); and
- 5. Appropriateness of budget request to attaining project objectives (5 points).

# **Specific Criteria for Johne's Disease Vaccination Modeling Applications (60 Points total):**

- 1. Technical merit of proposed predictive model(s) based on currently available information and data pertaining to a variety of relevant parameters (as described in Part IIC) (40 points).
- 2. Clarity and quality of proposed collaboration and communication with existing major programs and initiatives within the at-large Johne's Disease scientific community (20 points).

## **Specific Criteria for PHFD Applications (60 Points total):**

- 1. Technical merit of proposed collaborative research activities designed to determine the mechanisms of pathogenesis and the etiologic agents responsible for the syndrome identified as PHFD (as described in Part IIC) (15 points).
- 2. Capacity of proposed specialized facilities and collaborations to conduct work that may involve select agents or other high-consequence foreign animal disease agents (25 points).
- 3. Adequacy of proposed research and oversight protocols to ensure that work will be carried out in accordance with all relevant APHIS policies, regulations and guidance pertaining to foreign animal disease agents (20 points).

#### C. Conflicts of Interest and Confidentiality

During the peer evaluation process, extreme care will be taken to prevent any actual or perceived conflicts of interest that may impact review or evaluation. For the purpose of determining conflicts of interest, the academic and administrative autonomy of an institution shall be determined by reference to the current Higher Education Directory, published by Higher Education Publications, Inc., 6400 Arlington Boulevard, Suite 648, Falls Church, Virginia 22042. Phone: (703) 532-2300. Web site: <a href="http://www.hepinc.com/">http://www.hepinc.com/</a>.

Names of submitting institutions and individuals, as well as application content and peer evaluations, will be kept confidential, except to those involved in the review process, to the extent permitted by law. In addition, the identities of peer reviewers will remain confidential throughout the entire review process. Therefore, the names of the reviewers will not be released to applicants.

#### **D.** Organizational Management Information

Specific management information relating to an applicant shall be submitted on a one time basis, with updates on an as needed basis, as part of the responsibility determination prior to the award of a grant identified under this RFA, if such information has not been provided previously under this or another CSREES program. CSREES will provide copies of forms recommended for use in fulfilling these requirements as part of the preaward process. Although an applicant may be eligible based on its status as one of these entities, there are factors which may exclude an applicant from receiving Federal financial and nonfinancial assistance and benefits under this program (e.g., debarment or suspension of an individual involved or a determination that an applicant is not responsible based on submitted organizational management information).

#### PART VI—AWARD ADMINISTRATION

#### A. General

Within the limit of funds available for such purpose, the awarding official of CSREES shall make grants to those responsible, eligible applicants whose applications are judged most meritorious under the procedures set forth in this RFA. The date specified by the awarding official of CSREES as the effective date of the grant shall be no later than September 30 of the Federal fiscal year in which the project is approved for support and funds are appropriated for such purpose, unless otherwise permitted by law. It should be noted that the project need not be initiated on the grant effective date, but as soon thereafter as practical so that project goals may be attained within the funded project period. All funds granted by CSREES under this RFA shall be expended solely for the purpose for which the funds are granted in accordance with the approved application and budget, the regulations, the terms and conditions of the award, the applicable Federal cost principles, and the Department's assistance regulations (parts 3015 and 3019 of 7 CFR).

#### **B.** Award Notice

The award document will provide pertinent instructions and information including, at a minimum, the following:

- (1) Legal name and address of performing organization or institution to which the Administrator has issued an award under the terms of this request for applications;
- (2) Title of project;
- (3) Name(s) and institution(s) of PDs chosen to direct and control approved activities;
- (4) Identifying award number assigned by the Department;
- (5) Project period, specifying the amount of time the Department intends to support the project without requiring recompetition for funds;
- (6) Total amount of Departmental financial assistance approved by the Administrator during the project period;
- (7) Legal authority(ies) under which the award is issued;
- (8) Appropriate Catalog of Federal Domestic Assistance (CFDA) number;
- (9) Applicable award terms and conditions <a href="http://www.csrees.usda.gov/business/awards/awardterms.html">http://www.csrees.usda.gov/business/awards/awardterms.html</a> to view CSREES award terms and conditions;
- (10) Approved budget plan for categorizing allocable project funds to accomplish the stated purpose of the award; and

(11) Other information or provisions deemed necessary by CSREES to carry out its respective awarding activities or to accomplish the purpose of a particular award.

## C. Administrative and National Policy Requirements

Several Federal statutes and regulations apply to grant applications considered for review and to project grants awarded under this program. These include, but are not limited to:

7 CFR Part 1, subpart A—USDA implementation of the Freedom of Information Act.

7 CFR Part 3—USDA implementation of OMB Circular No. A-129 regarding debt collection.

7 CFR Part 15, subpart A—USDA implementation of Title VI of the Civil Rights Act of 1964, as amended.

7 CFR Part 331 and 9 CFR Part 121—USDA implementation of the Agricultural Bioterrorism Protection Act of 2002.

7 CFR Part 3015—USDA Uniform Federal Assistance Regulations, implementing OMB directives (i.e., OMB Circular Nos. A-21 and A-122, now codified at 2 CFR Parts 220 and 230) and incorporating provisions of 31 U.S.C. 6301-6308 (formerly the Federal Grant and Cooperative Agreement Act of 1977, Pub. L. No. 95-224), as well as general policy requirements applicable to recipients of Departmental financial assistance.

7 CFR Part 3017—USDA implementation of Governmentwide Debarment and Suspension (Nonprocurement) and 7 CFR Part 3021—Governmentwide Requirements for Drug Free Workplace (Grants).

7 CFR Part 3018—USDA implementation of Restrictions on Lobbying. Imposes prohibitions and requirements for disclosure and certification related to lobbying on recipients of Federal contracts, grants, cooperative agreements, and loans.

7 CFR Part 3019—USDA implementation of OMB Circular A-110, Uniform Administrative Requirements for Grants and Other Agreements With Institutions of Higher Education, Hospitals, and Other Nonprofit Organizations.

7 CFR Part 3052—USDA implementation of OMB Circular No. A-133, Audits of States, Local Governments, and Non profit Organizations.

7 CFR Part 3407—CSREES procedures to implement the National Environmental Policy Act of 1969, as amended.

29 U.S.C. 794 (section 504, Rehabilitation Act of 1973) and 7 CFR Part 15b (USDA implementation of statute) —prohibiting discrimination based upon physical or mental handicap in Federally assisted programs.

35 U.S.C. 200 et seq. —Bayh Dole Act, controlling allocation of rights to inventions made by employees of small business firms and domestic nonprofit organizations, including universities, in Federally assisted programs (implementing regulations are contained in 37 CFR Part 401).

# D. Expected Program Outputs and Reporting Requirements

Grantees are also required to submit initial project information and annual and summary reports to CSREES' Current Research Information System (CRIS). The CRIS database contains narrative project information, progress/impact statements, and final technical reports that are made available to the public. For applications recommended for funding, instructions on preparation and submission of project documentation will be provided to the applicant by the agency contact. Documentation must be submitted to CRIS before CSREES funds will be released. Project reports will be requested by the CRIS office when required. For more information about CRIS, visit the <a href="USDA/Current Research Information System">USDA/Current Research Information System</a> (http://cris.csrees.usda.gov/).

# PART VII—AGENCY CONTACT

Applicants and other interested parties are encouraged to contact <u>Dr. Gary B. Sherman</u>; telephone: (202) 401 - 4952; fax: (202) 401 - 6156; e-mail: <u>gsherman@csrees.usda.gov</u>; or <u>Dr. Peter Johnson</u>; telephone: (202) 401 - 1896; fax: (202) 205 - 3641; e-mail: <u>pjohnson@csrees.usda.gov</u>.

#### PART VIII—OTHER INFORMATION

#### A. Access to Review Information

Copies of reviews, not including the identity of reviewers, and a summary of the panel comments will be sent to the applicant PD after the review process has been completed.

# **B.** Use of Funds; Changes

#### 1. Delegation of Fiscal Responsibility

Unless the terms and conditions of the award state otherwise, the awardee may not in whole or in part delegate or transfer to another person, institution, or organization the responsibility for use or expenditure of award funds.

#### 2. Changes in Project Plans

- a. The permissible changes by the awardee, PD(s), or other key project personnel in the approved project shall be limited to changes in methodology, techniques, or other similar aspects of the project to expedite achievement of the project's approved goals. If the awardee or the PD(s) is uncertain as to whether a change complies with this provision, the question must be referred to the Authorized Departmental Officer (ADO) for a final determination. The ADO is the signatory of the award document, not the program contact.
- b. Changes in approved goals or objectives shall be requested by the awardee and approved in writing by the ADO prior to effecting such changes. In no event shall requests for such changes be approved which are outside the scope of the original approved project.
- c. Changes in approved project leadership or the replacement or reassignment of other key project personnel shall be requested by the awardee and approved in writing by the ADO prior to effecting such changes.
- d. Transfers of actual performance of the substantive programmatic work in whole or in part and provisions for payment of funds, whether or not Federal funds are involved, shall be requested by the awardee and approved in writing by the ADO prior to effecting such transfers, unless prescribed otherwise in the terms and conditions of the award.
- e. The project period may be extended by CSREES without additional financial support, for such additional period(s) as the ADO determines may be necessary to complete or fulfill the purposes of an approved project, but in no case shall the total project period exceed three years. Any extension of time shall be conditioned upon prior request by the awardee and approval in writing by the ADO, unless prescribed otherwise in the terms and conditions of award.
- f. Changes in Approved Budget: Unless stated otherwise in the terms and conditions of award, changes in an approved budget must be requested by the awardee and approved in writing by the ADO prior to instituting such changes if the revision will involve transfers or expenditures

of amounts requiring prior approval as set forth in the applicable Federal cost principles, Departmental regulations, or award.

## C. Confidential Aspects of Applications and Awards

When an application results in an award, it becomes a part of the record of CSREES transactions, available to the public upon specific request. Information that the Secretary determines to be of a confidential, privileged, or proprietary nature will be held in confidence to the extent permitted by law. Therefore, any information that the applicant wishes to have considered as confidential, privileged, or proprietary should be clearly marked within the application. The original copy of an application that does not result in an award will be retained by the Agency for a period of three years. Other copies will be destroyed. Such an application will be released only with the consent of the applicant or to the extent required by law. An application may be withdrawn at any time prior to the final action thereon.

## **D.** Regulatory Information

For the reasons set forth in the final Rule related Notice to 7 CFR part 3015, subpart V (48 FR 29114, June 24, 1983), this program is excluded from the scope of the Executive Order 12372 which requires intergovernmental consultation with State and local officials. Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the collection of information requirements contained in this Notice have been approved under OMB Document No. 0524-0039.

#### E. Definitions

For the purpose of this program, the following definitions are applicable:

For the purpose of this program, the following definitions are applicable:

<u>Administrator</u> means the Administrator of the Cooperative State Research, Education, and Extension Service (CSREES) and any other officer or employee of the Department to whom the authority involved is delegated.

<u>Authorized departmental officer</u> means the Secretary or any employee of the Department who has the authority to issue or modify grant instruments on behalf of the Secretary.

<u>Authorized representative</u> means the president, director, or chief executive officer or other designated official of the applicant organization who has the authority to commit the resources of the organization.

<u>Budget period</u> means the interval of time (usually 12 months) into which the project period is divided for budgetary and reporting purposes.

Department or USDA means the United States Department of Agriculture.

<u>Grant</u> means the award by the Secretary of funds to an eligible organization or individual to assist in meeting the costs of conducting, for the benefit of the public, an identified project which is intended and designed to accomplish the purpose of the program as identified in these guidelines.

<u>Grantee</u> means an organization designated in the grant award document as the responsible legal entity to which a grant is awarded.

<u>Peer review</u> means an evaluation of a proposed project for scientific or technical quality and relevance performed by experts with the scientific knowledge and technical skills to conduct the proposed work or to give expert advice on the merits of an application.

<u>Prior approval</u> means written approval evidencing prior consent by an authorized departmental officer.

<u>Project</u> means the particular activity within the scope of the program supported by a grant award.

<u>Project director</u> means the single individual designated in the grant application and approved by the Secretary who is responsible for the direction and management of the project.

<u>Project period</u> means the period, as stated in the award document, during which Federal sponsorship begins and ends.

<u>Research activity</u> means a scientific investigation or inquiry that results in the generation of knowledge.

<u>Secretary</u> means the Secretary of Agriculture and any other officer or employee of the Department to whom the authority involved is delegated.